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| APPLICATION NO.            | FI                | LING DATE  | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------|-------------------|------------|----------------------|---------------------|------------------|
| 10/605,352                 | 05,352 09/24/2003 |            | Samuel R. Levatino   | R212                | 2351             |
| 22692                      | 7590              | 12/10/2004 |                      | EXAM                | INER             |
| REGINAL                    |                   | ERTS JR    | SIRMONS, KEVIN C     |                     |                  |
| PO BOX 4535                |                   |            |                      |                     |                  |
| BATON ROUGE, LA 70821-4535 |                   |            |                      | ART UNIT            | PAPER NUMBER     |
|                            | ·,                |            |                      | 3763                |                  |
|                            |                   |            |                      |                     |                  |

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(s)                   |  |  |  |  |
|---|---|--------------------------------|--|--|--|--|
| Office Action Commence  | 10/605,352  | LEVATINO, SAMUEL R.            |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit                       |  |  |  |  |
| •   | Kevin C. Sirmons  | 3763                           |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply  | ears on the cover sheet with the c  | orrespondence address          |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                                |  |  |  |  |
| Status .  |   |                                |  |  |  |  |
| 1) Responsive to communication(s) filed on 01 Oc  | ctober 2004.  |                                |  |  |  |  |
| 2a)⊠ This action is <b>FINAL</b> . 2b)☐ This  | action is non-final.  |                                |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |   |                                |  |  |  |  |
| closed in accordance with the practice under E  | x parte Quayle, 1935 C.D. 11, 45  | 3 O.G. 213.                    |  |  |  |  |
| Disposition of Claims   |   |                                |  |  |  |  |
| 4)⊠ Claim(s) <u>1-8 and 10-20</u> is/are pending in the ap  | plication.  |                                |  |  |  |  |
| 4a) Of the above claim(s) is/are withdraw   | n from consideration.   |                                |  |  |  |  |
| 5) Claim(s) <u>16-20</u> is/are allowed.  |   |                                |  |  |  |  |
| 6)⊠ Claim(s) <u>1-8 and 10-15</u> is/are rejected.  |   |                                |  |  |  |  |
| 7) Claim(s) is/are objected to.   |   |                                |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or   | election requirement.   |                                |  |  |  |  |
| Application Papers  |   |                                |  |  |  |  |
| 9) The specification is objected to by the Examiner   | •<br>•  |                                |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  |   |                                |  |  |  |  |
| Applicant may not request that any objection to the o   | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). |                                |  |  |  |  |
| Replacement drawing sheet(s) including the correcti   | on is required if the drawing(s) is obj   | ected to. See 37 CFR 1.121(d). |  |  |  |  |
| 11) The oath or declaration is objected to by the Example 11.   | aminer. Note the attached Office  | Action or form PTO-152.        |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |                                |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b Some * c None of:   |   |                                |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |   |                                |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |   |                                |  |  |  |  |
| 3. Copies of the certified copies of the prior  | 3. Copies of the certified copies of the priority documents have been received in this National Stage   |                                |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).   |   |                                |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.  |   |                                |  |  |  |  |
|   |   |                                |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  | 4) Interview Summary  | (PTO-413)                      |  |  |  |  |
| 2) Notice of References Cited (* 10-032)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Da   | te                             |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date  | 5)  Notice of Informal Page 6) Other:   | atent Application (PTO-152)    |  |  |  |  |
|   |   |                                |  |  |  |  |

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#### **DETAILED ACTION**

# Specification

The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means- (or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see MPEP 2181 (Rev. 1, Feb.2000))

Appropriate correction is required.

## Claim Rejections - 35 USC § 112

Claims 5 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 5 and 13, it is unclear how vacuum is regarded as a therapeutic agent.

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# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 and 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwan.

Kwan discloses a microtube comprising: a tubular member (1); an interior axial opening (fig. 1); and a side port (3 and 2); Note: the device of Kwan is fully capable of performing the functions as set forth by applicant; as to claim 3, (5); as to claim 4-6, when the syringe applies a therapeutic agent (col. 3), it also applies the agent with pressure and a syringe action can be reversed to cause vacuum action. As to claim 7-10, 12-15, see above rejections.

Kwan discloses a micro tube substantially as claimed except for an outside diameter of about 10 to about one hundred microns, and an inside diameter of from about five to about fifty microns. It would have been an obvious matter of design choice to chance the size of the microtube, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

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### Response to Arguments

As to claim 1, the method of manufacturing is given little patentable weight in an apparatus claim. Furthermore, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to vary the dimensions of a microtube because Applicant has not disclosed that the specific dimensions provided an advantage, is used for a particular purpose not well known in the art, or solves a stated problem. One of ordinary skill in the art, additionally would have expected Applicant's invention to perform equally well with the device of Kwan because it is used for surgery and dentistry. Therefore, it would have been an obvious matter of design choice to modify the microtube of Kwan to obtain the invention as specified in claim 1.

As to claim 2, clearly the proximal end of the tubular member (1) is connected to a syringe or any other connecting means disclosed by applicant. The connecting means of applicant device and Kwan are substantially equivalent.

As to claim 3, clearly Kwan discloses a flange (5).

As to claim 4, clearly the therapeutic agent is pressurized once it leaves the syringe.

As to claim 5, In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a vacuum line) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

**4.** '

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See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, vacuum is vacuum. Applicant has not claimed that a specific amount of vacuum is required to remove blood, saliva, and/or fragments of enamel from the patient's mouth.

As to claim 6, clearly the therapeutic agent is a pharmaceutical agent (col. 1-3).

As to claims 7-8, see above remarks and the device of Kwan and Applicant's are substantially equivalent. Therefore, the device of Kwan is fully capable of functioning like applicant's device.

As to claims 10-15, see above remarks.

### Allowable Subject Matter

Claims 16-20 are allowable over the prior art of record.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

Kevin C. Sirmons

Primary Examiner

12/6/04